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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,647	09/04/2003	Robert A. VanTassel	4056	8112

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EXAMINER	
BUI, VY Q	

ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
05/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,647	VANTASSEL ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/5/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *2 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 2-3 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Election was made **without** traverse in the reply filed on 3/1/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (line 12) recites "blood **may** flow through the filtering membrane". It is not clear if claim 1 requires blood flowing through the filtering membrane or not. Clarification is required.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by Lesh et al-6,152,144.

As to claims 1, 4-6, Lesh-'144 (Fig. 6-8, 11-12; C 2: L 2-6; C 9: L 15-42, for example) shows a occluding device for prevention of **an embolic stroke** caused by **embolic material**

(blood clots, gas buble, solid tissue or the like, see C 4: L 18-20), in particular, formed in the **left atrial appendage** of a patient (abstract). Lesh-'144 device comprises mesh membrane 61/107, expandable support structure 65/103, which can be expandable by a balloon or by a self expanding mechanism (col. 9, lines 15-42) and a method substantially as recited in the claims.

Especially, Lesh-'144's (F 3a, 6-8; col. 2, lines 42-45) disclose mesh membrane 61/107 having pores sized up to **0.005" (or 0.127mm or 127 microns)** or pores sized up to **0.04" (or 1mm or 1000 microns)**. Inherently, mesh membrane 61/107 of Lesh-'144 must allow blood cells to flow through and filter any thrombus particles having a size bigger than the pore sizes (up to 127 microns or up to 1,000 microns) to go through.

Notice that blood red cells are about **6-8 micron or micrometers** and most white blood cells are about **10-12 microns** as indicated in two documents: (1). Red_blood_cell_size.pdf", and (2). "White_blood_cell.pdf", which were attached in the previous "non-final office action" (paper 9/16/2010).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al-6,152,144 in view of Bates-6,179,859 B1.

As to claim 1, Lesh-'144 (Fig. 6-8, 11-12; C 2: L 2-6; C 9: L 15-42, for example) shows a occluding device for prevention of **an embolic stroke** caused by **embolic material** (blood clots, gas buble, solid tissue or the like, see C 4: L 18-20), in particular, formed in the **left atrial**

appendage of a patient (abstract). Lesh-'144 device comprises mesh membrane 61/107, expandable support structure 65/103, which can be expandable by a balloon or by a self expanding mechanism (col. 9, lines 15-42) and a method substantially as recited in the claims. Especially, Lesh-'144's (F 3a, 6-8; col. 2, lines 42-45) disclose mesh membrane 61/107 having pores sized up to 0.005" (or 0.127mm or 127 microns) or pores sized up to 0.04" (or 1mm or 1000 microns).

Lesh-'144 does not **explicitly** state mesh membrane 61/107 for filtering emboli in a left atrial appendage sac in a patient. However, Bates-'859 (F 1-3E; C 4: L 30-38) discloses a filter sac 31 having pores preferably about **0.0012" (30 microns)** to filter embolic material. From Bates-'859's teaching, it is evident that a pore size of about 0.0012" (about 30 microns) is effective to filter embolic material. It would have been obvious to one of ordinary skill in the art to provide mesh membrane 61/107 of Lesh-'144 having pore sizes of about 30 microns to filter embolic material formed in the **left atrial appendage** of a patient, as this configuration would filter embolic particles bigger than about 30 microns in the **left atrial appendage** of a patient from flowing through the filter membrane 61/107 of Lesh-'144 to the blood stream of a patient and prevent the patient from suffering an embolic stroke.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al-6,152,144.

As to claim 7, Lesh-'144 discloses substantially a device and a method of preventing an embolic stroke substantially as recited in the claims except for removing the expandable structure through an opening in Lesh-'144's membrane 61 after expanding the support structure 65 (Fig. 6-8). However, Lesh-'144 (col. 9, lines 15-33) discloses a balloon to expand support structure 65 and a lumen with a self sealing valve in hub 73 for receiving a guidewire of guiding member (Col. 10, lines 3-8). The self sealing valve will prevent a passage of fluid or embolic

material once the guidewire or guiding member is removed from the lumen. It would have been obvious to one of ordinary skill in the art to provide balloon catheter through the lumen in hub 73 to expand the support structure 65 and then withdraw the balloon from a left atrial appendage after the support structure 65 has been expanded by the balloon, as the lumen in hub 73 is the passage way available for introducing and removing the balloon catheter.

Response to Arguments

Applicant's arguments filed 2/15/2011 have been fully considered but they are not persuasive.

Section 102 &/ rejections: the applicant argued that: "In Applicant's view the best way to visualize a structure of Lesh is that it consists of many porous layers laminated together so that the pores overlap enough times and enough directions so that there is in fact no fluid path from one side of the membrane to the other. In order words, the pores form small craters on the surface of what ultimately becomes an impervious surface. In Applicant's view it is inappropriate to argue that one of ordinary skill would simply realign pore sizes to permit fluid passage since this is explicitly not the desired result of Lesh. A solution proposed in the claims of Applicant is completely contrary to the problem as understood by Lesh. In Lesh's view it is vital that the membrane be impervious to prevent all embolic material, regardless of size, from leaving the left atrial appendage. It is Applicant's recognition that porosity not pore size improves the stability of the implant that is at odds with the teachings of Lesh and is an independent invention.".

As set forth above, the pore sizes of mesh membrane 61/107 of Lesh-'144 as shown in F 3a, 6-8 are up to 0.04" or about 1000 microns = 1 mm. These pores will inherently allow

blood going through and inherently filter thrombus particles having sizes bigger than the pore sizes from going through the mesh membrane.

To the contrary to the above Applicant's arguments, there is nothing in Lesh-'144 that teaches membrane 61/107 is formed of many porous layers laminated together so that the pores overlap enough times and enough directions so that there is in fact no fluid path from one side of the membrane to the other to form an impervious surface.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773